Fingertip Pulse Oximeter

Geratherm®
oxy control

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INSTRUCTION FOR USE

Please read carefully before using

GT-300C203

CE 0197

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GENERAL DESCRIPTIONS

Oxygen Saturation is a percentage of Oxyhemoglobin (HbO2) capacity, compounded with oxygen, by all combinative hemoglobin (Hb) capacity in blood. In other words, it is consistency of Oxyhemoglobin in blood. It is a very important parameter for the Respiratory Circulation System. Many respiratory diseases can result in oxygen saturation being lowered in human blood. Additionally, the following factors can reduce oxygen saturation: Automatic regulation of organ dysfunction caused by Anesthesia, Intensive Postoperative Trauma, injuries caused by some medical examinations. That situation might result in light-headedness, asthenia, and vomiting. Therefore, it is very important to know the oxygen saturation of a patient so that doctors can find problems in a timely manner.

The fingertip pulse oximeter features low power consumption, convenient operation and portability. Place one fingertip into the photoelectric sensor for diagnosis and the pulse rate and oxygen saturation will appear on the display. It has been proven in clinical experiments that it also features high precision and repeatability.

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⚠ PRECAUTIONS

1. Do not use the pulse oximeter in an MRI or CT environment.
2. The pulse oximeter must be kept out of reach of children. Small parts can be detached from the device. These can be swallowed by children or cause suffocation by inhalation of the parts.
3. Operating Geratherm oxy control can be influenced by the use of an electrosurgical unit (ESU).
4. Do not use the pulse oximeter in situations where alarms are required. The device has no alarm. It is not suitable for continuous monitoring. Explosion Hazard: Do not use the pulse oximeter in an explosive atmosphere.
5. Do not use the device if it has damaged partsExplosion hazard: Do not use the pulse oximeter in an explosive atmosphere.
6. The pulse oximeter is provided only as an aid for patient diagnosis. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
7. Prolonged use or the patient's condition may require changing the sensor site periodically. Change the sensor site and check skin integrity, circulatory status, and correct alignment every 4 hours.
8. Inaccurate measurements by autoclaving, sterilizing with ethyl oxide or immersing the sensors in liquid may cause inaccurate readings.
9. Keep the oximeter in a dry environment.
10. The following factors can affect the SpO2 measurements and lead to inaccurate values:
    - Significant levels of dysfunctional hemoglobin (such as carboplatin hemoglobin or methemoglobin)
    - Intravascular dyes such as indocyanine green or methylene blue
    - High ambient light (the sensor area protected from direct sunlight)
    - Excessive patient movement
    - Venous pulsations
    - Placement of a sensor on an extremity with a blood pressure cuff, an arterial catheter or intravascular line
    - Patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia
    - Patient has a cardiac arrest or is in shock
    - Nail polish or artificial fingernails
    - Too cold or dirty fingers

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APPLICATION OF THE PRODUCT AND INTENDED USE

Geratherm® pulse oximeter is a portable non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult and pediatric patients in hospitals, hospital-type facilities, and home environments. It is not for continuous monitoring.

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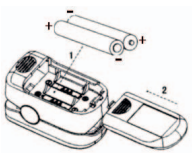
HOW TO REPLACE THE BATTERY

1. Install two AAA batteries into the battery compartment. Match the plus (+) and minus (-) signs in the compartment. If the polarities are not matched, damage may be caused to the oximeter.
2. Slide the battery door cover horizontally along the arrow shown as the picture.



⚠ **Note:** The pole orientation of the batteries must be as shown in the in Figure, otherwise the device may be damaged.
Please insert or remove the batteries in the correct order, otherwise the devices tab could be damaged. Please remove the batteries if the oximeter is no longer in use. If the battery status indicator lights up, replace the batteries in time.

⚠ **Warning: Do not dispose the battery in normal domestic waste! Keep out of reach of young children. Do not dispose of the battery in a fire. It may explode.**

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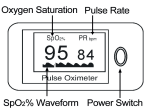
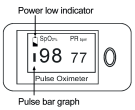
DISCRIPTION OF DISPLAY





The heart rate-bar flashes according to the displayed pulse rate.

HOW TO OPERATE

1. Install two AAA batteries according to the Battery Installation instructions.
2. Squeeze the device at the rear to open the front part to accommodate the finger.
3. If your finger is in the oximeter, your nail must be facing up.
4. After inserting the finger release the rear section again.
5. Press the power switch in the front of the device once.
6. While the oximeter is measuring, you should not move your finger and keep yourself quiet.
7. The display will read the corresponding measured values.

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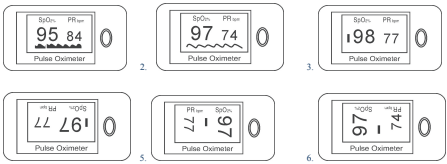
After turning on the Oximeter, each time you press the power switch, the Oximeter will switch to another display mode. There are 6 display modes shown as follows:



Press the power button for a longer time (more than a second) to adjust the brightness of the display. By holding the power button the display gradually changes the brightness of the oximeter. There are 10 levels of brightness. Level 4 is the default brightness.

The pulse oximeter comes with a protective sleeve to protect it from dirt and impacts.

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EVALUATION OF THE MEASURED VALUES

Healthy patients have an oxygen saturation of 96-98%. Values below 95% can already show a disease indication and require a medical treatment. If your oxygen saturation is below 95%, please consult your doctor.
Normal pulse rates depend on the age and fitness level of a person.
Below are some reference values for a normal pulse rate:

- Children under 1 year: 100 - 160 bpm
- Children 1-10 years: 70 - 120 bpm
- People over 10 years: 60 - 100 bpm
- Trained people / athletes: 40 - 60 bpm

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SPECIFICATIONS

1. Model-Nummer:
   GT-300C203

2. Anzeigetyp:
   1-colored OLED-display

3. SpO2:
   Display range: 0 to 99%
   Measuring range: 70 to 99%
   Accuracy: 70% to 99%: ±3%; 0% to 69% no definition
   Resolution: 1%

4. Pulse Rate:
   Display range: 0 to 254BPM
   Measuring range: 30 to 235 BPM
   Accuracy: 30 to 99bpm, ±2bpm; 100 to 235bpm, ±2%
   Resolution: 1BPM

5.

	Wavelength	Radiant Power
RED	660±2nm	1.8mW
IR	940±10nm	2.0mW

   NOTE: The information about wavelength range can be especially useful to doctors.

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6. Power Requirement:
   Two AAA 1.5V, 600mAh alkaline batteries
   Power consumption: Less than 30mA
   Battery status indicator:
   Alkaline batteries could be continuously operated as long as 30 hours

7. IP Classification:
   IPX1 (Protection against vertically falling drops of water)

8. Dimensions:
   Length: 58 mm; Width: 32 mm; Height: 34 mm
   Weight: 50g (including 2 Batteries)

9. Environmental Requirements:
   Operation Temperature: +5 bis +40 °C
   Storage Temperature: -20 bis +55 °C
   Ambient Humidity: ≤ 80 % bei Einsatz
   ≤ 93 % bei Aufbewahrung
   Atmosphere pressure: 86 kPa bis 106 kPa

10. quality Guarantee: Geratherm® is certified according to Directive 93/42/EEC and EN ISO 13485 and entitled to the application of the mark CE 0197 (Notified Body TÜV Rheinland LGA Products GmbH). EN 9919:2005 Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

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POSSIBLE PROBLEMS AND SOLUTIONS

Problem	*Possible Reason*	*Solution*
SpO_2 or PR cannot be shown normally.	1. Finger is not inserted correctly. 2. Patient's oxyhaemoglobin level is too low to be measured	1. Try inserting the finger again. 2. Try several more times if you are sure that there is no problem with the device. Please go to a hospital in good time to obtain a precise diagnosis.
SpO_2 or PR is shown unstably	1. Finger might not be inserted far enough. 2. Finger is trembling or the patient's body is moving.	1. Try inserting the finger again. 2. Try not to move.
The oximeter Cannot be switched On.	1. Battery power may be inadequate or not be there at all. 2. Batteries may have been inserted incorrectly. 3. The oximeter might be damaged.	1. Please replace batteries. 2. Please reinsert the batteries. 3. Have the device tested by the manufacturer
„Finger out" Displayed on screen	1. There is no finger on the pulse oximeter or finger is not positioned properly.	1. Place your finger in the oximeter.
Indication lamps suddenly go off	1. The product is automatically switched off if no signal is detected for longer than 8 seconds. 2. Low power/ Batteries empty.	1. Normal 2. Replace the batteries.
"Error3" or "Error4" Displayed on screen	1. Low power/ Batteries empty 2. Receiving sensor shielded or sensor damaged.	1. Insert new batteries. 2. Have the device tested by the manufacturer.
"Error7" displayed on screen	1. Low power/ Batteries empty 2. Infrared sensor damaged.	1. Change the batteries. 2. Have the device tested by the manufacturer.

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CLEANING INSTRUCTIONS

Please use medical alcohol to clean the synthetic material touching the finger inside the oximeter, and clean the test finger before and after using. Please clean the surface of pulse oximeter for every use.

DISPOSAL

Observe the applicable regulations when disposing of the device and batteries. This product must not be disposed of together with domestic waste.

All users are obliged to hand in all electrical or electronic devices, regardless of whether or not they contain toxic substances, at a municipal or commercial collection point so that they can be disposed of in an environmentally acceptable manner.

Please remove the batteries before disposing of the device/unit. Do not dispose of old batteries with your household waste, but at a battery collection station at a recycling site or in a shop.

WARRANTY

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This pulse oximeter is guaranteed for 2 years from the date of purchase against manufacturer's defect under conditions of normal use. Following the instructions precisely will ensure that the device functions reliably for many years.

If your pulse oximeter does not function properly due to defective parts or assembly we will repair it free of charge.

All parts are covered by this warranty. The warranty does not cover damage to your unit due to improper handling. The manufacturer recommends that the accuracy of the device be checked by an authorized laboratory every 2 years. Adhere to the applicable regulations when disposing of the device.

SYMBOL INDEX

- = Attention, consult accompanying documents
- = Type BF applied part
- = No SPO_2 Alarm
- = Keep dry
- = The device must not be disposed of with household waste
- = Store between 10 % and 93 % R.H.
- = Store between -20 °C and +55 °C
- LOT = Batch code (mm/yyyy; month/year)
- SN = Serial number
- = Manufacturer
- = Date of Manufacture

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APENDIX

Information on electromagnetic compatibility (EMC)

Electronic devices such as PCs and mobile phones can lead to the exposure of medical devices in operation to electromagnetic interference from other devices. This can lead to malfunction of the medical device and create a potentially unsafe situation.
Medical devices should also not interfere with any other devices.

The EN 60601-1-2 standard regulates the requirements for EMC (electromagnetic compatibility) and defines the levels of immunity to electromagnetic
interference and the maximum electromagnetic emission levels for medical devices.

This pulse oximeter, which is manufactured by Geratherm Medical AG, complies with the EN 60601-1-2:2007 standard in relation to both immunity and emissions.
However, special precautions should be observed:

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Guidance and manufacturer´s declaration - electromagnetic emissions. *The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:*

Emissions Test	***Compliance***	***Electromagnetic environment - guidance***
RF-emissions CISPR 11	Group 1	RF energy is used only to maintain device's operation. Therefore, its RF emissions are so low that it's not likely to cause any interference in nearby electronic equipment.
RF-emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applied	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applied	

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Guidance and manufacturer´s declaration – electromagnetic immunity. *The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:*

Immunity test	*IEC 60601 - test level*	*Compliance level*	*Electromagnetic environment - guidance*
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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Recommended separation distances between portable and mobile RF communication equipment and the device.
The device is intended for use in an electromagnetic environment where radiated RF disturbances are under control. User can help prevent electromagnetic interference by keeping the device at a minimum distance from portable and mobile RF communications equipment (transmitters). Below table details the maximum output power of transmitter:

Rated maximum output power of transmitters in Watt	*Separation distance according to frequency of transmitter / m*	
	80 MHz - 800 MHz $d = 1,2\sqrt{P}$	800 MHz - 2,5 GHz $d = 2,3\sqrt{P}$
0,01	0,1167	0,2334
0,1	0,3689	0,7378
1	1,1667	2,3334
10	3,6893	7,3786
100	11,6667	23,3334

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer´s declaration - electromagnetic immunity. *The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:*

Immunity test	***IEC 60601-test level***	***Compliance level***	***Electromagnetic environment - guidance***
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Empfohlener Trennungsabstand: d= 1.2 √P d = 1.2√P 80 MHz to 800 MHz d = 2.3√P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b
Interference may occur in the vicinity of equipment marked with the following symbol:			

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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GUIDANCE AND MANUFACTURER´S DECLARATION – ELECTROMAGNETIC IMMUNITY

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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